

To: Troy Hopps[troy_hopps@bd.com]
Cc: Dave Hickey[Dave_Hickey@bd.com]
From: Frank Wang[/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E2C0F216449342C2A32DB5EBFA0E11DC-FWANG]
Sent: Tue 5/26/2020 10:01:30 PM (UTC-04:00)
Subject: Re: Shipment of serology tests for BD

Hi, Troy:
Thank you for your note.
Please see my comments on the note.

- To ensure we have the 1.4M tests available for sale in June , we agreed that BM will ship the 1.4M tests from China to US within the next two weeks in a series of shipments (500k/500k/400k) and have the product put on quarantine hold once it arrives in the us for the FDA and customs release.

Yes. We plan to ship 1.4 M in three shipments. We need to do a final check with FDA if we can do “importing and exporting” (for BioMedomics’s other outside US customers) and quarantine BD shipment at the same time. Andy will do the check tomorrow. Andy will also check with US Customs about our current two 9000 tests shipments which are on-hold and figure out if this quarantine process will work.

- Once the FDA issues an EUA and any label changes, BM will print the new IFU and update all quarantined kits with the new information. Once complete, this should provide the rationale to the FDA to release the product. BD will arrange pickup of the kits from BM for distribution to Henry Schein.

Yes. We will do it. We do not know if we can get goods on quarantine at BioMedomics site. If it is Quarantined at airport, the re-kitting will be a challenge work.

- Should there be any concerns around this process with the FDA, Dave offered to send a note to Tim Stenzel at the FDA to help clarify this process. Frank to draft a message for Dave to send to the FDA.

Yes. Thank Dave’s offer.

- With respect to Europe and Rest of World quantities, we agreed that BD would be able to place a PO for 1M tests for the month of June. 600K tests would be sent to Europe and the balance to be distributed to other countries. Should we choose the balance be sent to Latin America, BM would receive the product at their facility in NC for quality verification then export to Latin America, not for US use. Frank to confirm volumes by tomorrow.

Yes. I already confirmed that we can ship additional 1 M tests to BD Europe.

- With respect to volumes of tests available for BD, we agreed that for July to September, BM would provide 2M tests for the US market and 1.5M tests for OUS. PO’s to be issued.

Yes. We already discussed this before and greed. We will finalize this on a formal agreement.

- Lastly, Frank you mentioned that to fulfill demand, you need support from BD to acquire more nitrocellulose for manufacturing. Dave to reach out to procurement for their support in speaking with Satorius to prioritize BM orders. You require 200 rolls/mth in order to supply the 3.5M units to BD.

Yes. Thank you for the support. We need 200 rolls per month to support just BD’s orders. We need 600 rolls in total per month for our Chinese company.

Thanks and talk to you later.

Frank Wang, Ph.D.
CEO



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From: Troy Hopps <troy_hopps@bd.com>

Date: Tuesday, May 26, 2020 at 7:43 PM

To: Frank Wang <fwang@biomedomics.com>

Cc: Dave Hickey <Dave_Hickey@bd.com>

Subject: Shipment of serology tests for BD

Frank, just wanted to follow up on our discussion today regarding shipment of your serology tests to both US and Europe to BD for distribution.

- To ensure we have the 1.4M tests available for sale in June, we agreed that BM will ship the 1.4M tests from China to US within the next two weeks in a series of shipments (500k/500k/400k) and have the product put on quarantine hold once it arrives in the US for the FDA and customs release.
- Once the FDA issues an EUA and any label changes, BM will print the new IFU and update all quarantined kits with the new information. Once complete, this should provide the rationale to the FDA to release the product. BD will arrange pickup of the kits from BM for distribution to Henry Schein.
- Should there be any concerns around this process with the FDA, Dave offered to send a note to Tim Stenzel at the FDA to help clarify this process. Frank to draft a message for Dave to send to the FDA.
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Please let me know if I missed something or incorrectly captured any wrong notes.

Thanks

Troy



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